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10/605,126	09/10/2003	Andrew M. Hoff	1372.23.PRWOUS	2125

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EXAMINER	
BHATIA, AARTI	
ART UNIT	PAPER NUMBER
3763	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/605,126	HOFF ET AL.	
	Examiner	Art Unit	
	AARTI BHATIA	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/17/2008 and 4/17/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-11 and 14-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-11, and 14-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the second Office action based on the 10/605,126 application filed on 10 September 2003. Claims 1, 3-11, and 14-28, as amended on 3/17/2008, are currently pending and have been considered below.

Response to Amendment

Claim Objections

1. Claims 3 and 4 are objected to because of the following informalities: Claims 3 and 4 depend on claim 2, which is a cancelled claim. Claims 3 and 4 are treated as depending from claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-8, 10, 14-15 and 19-28 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,318,514 to Hoffmann.

With respect to claim 1, Hofmann discloses a device for electromanipulation of chemical species in vivo relative to a target tissue (abstract) comprising: an substantially planar nonconductive (column 2, lines 39-44) sheet (22) conformable (via pins 28) to the surface of the target tissue (column 2, lines 61-63); a plurality of electrode elements

(18) secured in spaced art relation on the array base (figures 2 and 3), the electrode elements adapted to be coupled to an electrical source (column 2, lines 49-50).

With respect to claim 3, Hofmann discloses the device of claim 1 wherein the plurality of electrode elements are integral to the sheet (column 2, lines 39-44).

With respect to claim 4, Hofmann discloses the device of claim 1 wherein the plurality of electrode elements project from the sheet towards the target tissue (figure 3).

With respect to claim 5, Hofmann discloses the device of claim 1 wherein the electrode elements are independently addressable (figure 3).

With respect to claim 6, Hofmann discloses the device of claim 1 wherein the electrode elements are addressable as one or more sets (figure 2).

With respect to claim 7, Hofmann discloses the device of claim 1 wherein the sheet is substantially conformable to facilitate contact between the electrodes and the target tissue (column 2, line 43).

With respect to claim 8, Hofmann discloses the device of claim 1 wherein the sheet is substantially rigid with a geometric shape adapted to facilitate contact between the electrodes and a corresponding target tissue (column 2, line 43).

With respect to claim 10, Hofmann discloses the device of claim 1 further comprising one or more fluid reservoirs (14) adapted to deliver chemical species to the target tissue (column 2, line 36).

With respect to claim 14, Hofmann discloses the device of claim 10 wherein the chemical species are released from the one or more fluid reservoirs responsive to a predetermined schedule (column 4, lines 10-24).

With respect to claim 15, Hofmann discloses the device of claim 10 wherein the chemical species are released from the one or more fluid reservoirs responsive to a predetermined time (column 4, lines 10-24).

With respect to claim 19, Hofmann discloses the device of claim 1 further comprising: at least one external reservoir adapted to hold chemical species (14); and at least one conduit (32) fluidly coupling the at least one reservoir to the array base whereby the chemical species are delivered through the at least one conduit to the array base for delivery to the target tissue (column 2, lines 57-60).

With respect to claim 20, Hofmann discloses the device of claim 1 further comprising a thin film of chemical species (20) on the array base whereby the chemical species are delivered to the target tissue when the array base is coincident to the target tissue (column 2, lines 57-60).

With respect to claim 21, Hofmann discloses the device of claim 20 wherein the chemical species are retained within the thin film by absorption means (column 2, lines 57-60).

With respect to claim 22, Hofmann discloses the device of claim 21 wherein the chemical species are released from the thin film by application of an energy means (column 3, lines 4-5).

With respect to claim 23, Hofmann discloses a device for manipulation of chemical species in vivo relative to a target tissue comprising: a substantially planar nonconductive sheet (22) conformable to topography of the surface of the target tissue (column 2, lines 61-63); a plurality of electrode elements projecting from the sheet

towards the target tissue (figure 3), the electrode elements addressable individually, the plurality of electrodes adapted to be coupled to an electrical source (column 2, lines 49-50); a control means interposed between the electrical source and the plurality of electrode elements and in circuit communication therein (12), the control means adapted to establish an electrical potential between at least two electrodes; and a delivery means adapted to introduce chemical species to the target tissue (column 3, lines 33-41).

With respect to claim 24, Hofmann discloses a method for electromanipulation of chemical species in vivo relative to a target tissue comprising the steps of: placing at least one substantially planar nonconductive sheet (22) conformable to topography of the surface of the target tissue coincident to the target tissue (column 2, lines 61-62), the at least one sheet (22) containing a plurality of electrode elements (18), (column 3, lines 5-8); establishing an electrical potential between at least two electrode elements in the plurality of electrode elements; providing a chemical species coincident to the target tissue (column 3, lines 4-5); controlling the electrical potential whereby the chemical species are delivered to the target tissue (column 3, lines 9-19; lines 33-41).

With respect to claim 25, Hofmann discloses the method of claim 24 wherein the electrical potential affects electromigration of the chemical species to the target tissue (column 3, lines 4-5).

With respect to claim 26, Hofmann discloses the method of claim 24 wherein the electrical potential affects electroporation of the target tissue (column 3, lines 20-32).

With respect to claim 27, Hofmann discloses the method of claim 24 wherein the electrical potential affects both electroporation of the target tissue and electromigration of the chemical species to the target tissue in substantially concurrent synchronization (column 3, lines 20-32).

With respect to claim 28, Hofmann discloses the method of claim 24, further comprising the steps of: establishing a predetermined sequence of electrical potentials for the plurality of electrode elements; and executing the predetermined sequence (column 4, lines 10-24).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann (U.S. Patent No. 5,318,514).

With respect to claim 9, Hofmann discloses the device of claim 1 except wherein the electrode elements are spaced together in sufficient proximity to insure that a peak power of less than 1 kilowatt is needed for electromanipulation of the target tissue. Hofmann does teach using a low voltage (with a field strength from about 0.2 kV/cm to about 20 kV/cm) in claim 1, however Hofmann is silent to the spacing of the electrode elements. It would have been obvious to one having ordinary skill in the art at the time the invention was made to arrange the electrode elements in order to achieve the desired output from the electromanipulation device.

With respect to claim 11, Hofmann discloses the device of claim 1 except wherein the electrical source (12) is integrated within the array base (12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to integrate the electrical source into the array base, since it has been held that forming

in one piece an article which has been formerly in two pieces and put together only involves routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1993).

6. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann (U.S. Patent No. 5,318,514) in view of U.S. Patent 5,284,136 to Hauck et. al.

Hofmann discloses the device of claim 10 wherein the chemical species are released from the one or more fluid reservoirs responsive to a predetermination. Hofmann fails to disclose this release in response to a metabolic condition. Hauk et. al. teaches that metabolic conditions can be a signal for electrical responses in an electrical biomedical apparatus. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of Hofmann by making responsive to metabolic conditions so that the device is effective when it is needed due to a change in the patient's metabolic state (column 2, lines 65-68).

7. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann (U.S. Patent No. 5,318,514) in view of U.S. 2004/0039343 to Eppstein et. al.

Hofmann discloses the device of claim 1 but fails to teach at least one micro plunger adapted to deliver chemical species to the target tissue, whereby chemical species held with the at least one micro plunger are released through the at least one porous electrode element to the target tissue. Eppstein teaches a micro reservoir (figure 24) which is used with an electroporation device for drug delivery. It would have been obvious to one having ordinary skill in the art at the time the invention was made

to modify the invention of Hofmann by adding micro plungers so that multiple substances can be delivered or analyzed by the electromanipulation device (paragraphs 160, 174).

Response to Arguments

1. The objection to the drawings has been withdrawn in view of the Applicant's amendments.

2. The objection to the claims has been withdrawn in view of the Applicant's amendments.

3. The rejection of claims 12-16 under the first paragraph of 35 U.S.C. §112 has been withdrawn in view of the Applicant's amendments.

4. Applicant's arguments filed 3/17/2008 have been fully considered but they are not persuasive.

5. Applicant argues that Hoffman does not anticipate claims 1, 23, and 24 as now amended. The Examiner disagrees. The Examiner finds the planar support member (22) of Hoffman to be a conformable sheet, as it is able to conform to the skin it is treating, but movement of the pins (28).

6. Applicant argues that a prima facie case of obviousness has not been established for claims 9, 11, 14, 15, 16, 17, and 18 because the cited references fail to disclose all the elements of the applicant's invention. However, as applicant also states, a prima facie case of obviousness over the prior art cited must teach or suggest all the

claim limitations. As explained above, the prior art cited does indeed teach **or suggest** all the claim limitations.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARTI BHATIA whose telephone number is (571)270-5033. The examiner can normally be reached on Monday-Thursday 8:00am -6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aarti Bhatia/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763